

### **REMARKS**

In this Amendment, Applicant has cancelled Claims 53 and 54, without prejudice or disclaimer, and has amended Claims 52, 55 – 59, 61, 64, 67 - 80 and 93. Claims 52, 67, 76, 77, 80 and 93 have been amended to further specify the invention. Claims 55, 58, 59, 68 and 69 have been amended to rephrase certain expressions. Claims 58 and 71 have been amended to correct clerical errors. In addition, Claims 55 – 59, 61, 64, 67 - 80 and 93 have been amended to proper dependent form. It is respectfully submitted that no new matter has been introduced by the amended claims. All claims are now present for examination in view of the accompanying remarks.

The specification has been amended to rephrase certain sentences and correct clerical errors. The amendments to the specification are entirely editorial in nature. It is respectfully submitted that no new matter has been introduced by the amended specification.

Favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

### **ELECTED INVENTION AND SPECIES:**

Claims 58 and 59 have been objected as non-elected species. Applicant respectfully submits that Claims 58 and 59 were elected among Claims 52-65 and 67-80 as Group III, which requires anti-stress agent and amino acid. In addition, Mifepristone (Claim 59) was elected as the second anti-stress agent in the election of species. Claims 58 and 59 are readable on this species, and Claim 58 is the generic claim to this species. Due to their dependency on Claim 52 as presently claimed, amino acid is required. Mifepristone is an antiprogesterin, but it is also classified as a glucocorticoid inhibitor. Claims 58 and 59 in present forms have antecedent basis. Therefore, withdrawal of the objections to Claims 58 and 59 is respectfully requested

### **REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:**

Claims 53, 55, 67 – 69 and 76 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

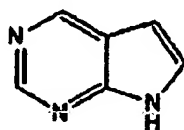
Applicant traverses the rejection. It is respectfully submitted that in view of presently claimed invention, the rejection has been overcome. In particular, Claim 53 has been cancelled without prejudice or disclaimer. “Corticotropin reducing agent” in Claim 58 has been corrected to “Corticotropin releasing agent.” It has the support in the specification (page 11, line 38). “CRH 9-41” in Claim 55 is not a trade name. It refers to alpha-helical corticotropin releasing hormone (CRH) antagonist, which is well known in the art. Claim 67 – 69 has been amended to specify the concentration and amount of antistress agent. The amount of agent present in the composition can be readily calculated based on the live weight information given in the specification (page 14, lines 12 – 18). Claim 76 has been amended to specify one embodiment of the invention. There is sufficient support in the specification (page 15, line 12).

Claims 52-54, 61, 64, 67 – 80 and 93 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention by utilizing functional language open to wide interpretation.

Applicant traverses the rejection. It is respectfully submitted that in view of presently claimed invention, the rejection has been overcome. In particular, the meaning of “antistress agent” has been defined in the specification as referring to compounds or compositions effective in reducing stress. The definition specifically stated that agents simply acting as nutritional modifiers such as foodstuffs are not included (page 11, lines 26 – 35). In addition, “antistress agent” is a term used and accepted in the art. For example, US 5,937,790 (Ito et al) cited by Examiner uses the term “antistress agent” (col. 1, line 14; col. 14, line 59). Moreover, in the present claims, “antistress agent” is specified as selected from pyridyl propanones, antiprogestins, benzoylamino dipropylamino oxopentanoics, benzodiazepines and corticotropin releasing factor (CRF) antagonists. The terms used in Claims 70, 72, and 78 are generally accepted and well known in the art of the field of the present invention. Claim 77 has been

amended to specify different embodiments of slow release composition. Claims 71, 74, 76 and 79 specify the components and the metes and bounds of the claims are clear. Claim 80 has been amended to specify that each component can be present independently or in combination with others. Claim 93 has been limited to animal feedstuff. Exemplification of mifepristone with metyrapone, vitamin C and amino acids isoleucine, valine and leucine in Claim 61 is provided in Experiment 13 (page 31). The Example 13 uses a controlled calorie volume matched glucose solution. Therefore, the combination is supported by the example in the specification.

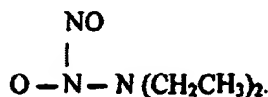
Examiner requested Applicant to provide the structures for compound in Claims 71 and 79. Claim 71 has been amended to provide the proper spelling for "pyrrolopyrimidine." The general structure is as follows:



pyrrolo-[2,3-d]-pyrimidine

The attachments points may vary. Therefore, pyrrolopyrimidines are a group of compounds sharing similar general structure, rather than a specific compound.

Regarding "L-arginine diethylamine nitric oxide complex" (DEA/NO complex) in Claim 79, the formula is 1,1-diethyl-2-hydroxy-2-nitrosohydrazine and the structure is as follows:



Applicant respectfully submits an article discussing the DEA/NO complex (see attached: Zhou et al.; Inhibitory Effects of Nitric Oxide and Nitrosative Stress on Dopamine-β-Hydroxylase; The Journal of Biological Chemistry, Vol. 275, No. 28). The L-arginine complex is formed when reacted under culture conditions and the structure of the same would be readily apparent to a person with ordinary skill in the relevant art.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 112 is respectfully requested.

**REJECTION UNDER 35 U.S.C. § 102(b)**

Claims 52, 53, 61, 64, 67 – 69, 75, 80 and 93 have been rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by the Schaefer et al (US 5,728,675), hereinafter Schaefer. Applicant traverses the rejection.

At first, Claim 53 has been cancelled. The rejection therefore is moot. Secondly, Claim 52 has been amended to limit “antistress agent” to be selected from pyridyl propanones, antiprogestins, benzoylamino dipropylamino oxopentanoics, benzodiazepines and corticotropin releasing factor (CRF) antagonists. Schaefer discloses an antemortem stress supplement containing one or more sources of electrolytes including sodium, potassium and magnesium, one or more sources of amino acids; and a source of tryptophan. Obviously, Schaefer does not disclose the specific components as required in Claim 52. Contrary to Examiner’s understanding, the “gamma amino butyric acid potentiators, antiglutaminergics, and serotonergics” as required by some claims of the present invention are not disclosed in Schaefer. Due to their dependency on Claim 52, Claim 61, 64, 67 – 69, 75, 80 and 93 are also distinguished from the disclosures in Schaefer.

Therefore, the rejection under 35 U.S.C. § 102(b) has been overcome. Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully requested.

**REJECTIONS UNDER 35 U.S.C. § 103:**

Claims 52 – 57, 61, 67, 68, 80 and 93 have been rejected under 35 U.S.C. § 103, as allegedly being obvious and unpatentable over Blackburn (WO 82/0041) in view of Walser (WO 95/30418) or Ito et al (US 5,937,790) and Daley et al ‘93. Applicant traverses the rejection.

Blackburn discloses a therapeutic amino acid preparation for the treatment of stress and injury. Specifically, the pharmaceutical preparation contains 70% to 100% of the branched chain amino acids valine, leucine and isoleucine. The amino acids are said to promote protein

synthesis in a stressed body. The compositions are formulated with a variety of diluents, excipients, carriers and infusion solutions and pH adjusters. However, there is no suggestion or motivation that these amino acids should be used together with anti-stress agents, especially pyridyl propanones, antiprogestins, benzoylamino dipropylamino oxopentanoics, benzodiazepines and corticotropin releasing factor (CRF) antagonists as required in the present invention.

Walser discloses a method for treating HIV by administering an agent that suppresses endogenous production of glucocorticoids together with a replacement glucocorticoid. The agent includes metyrapone and mifepristone. However, stress is not specifically mentioned as being treated. There is no suggestion or motivation to use the method disclosed in Walser to treat stress. Examiner may assume that HIV treatment itself causing stress. However, the present invention specifically defined that the stresses being treated are stresses from injury, trauma, surgery, hunger, thirst, fatigue, thermal extreme stress (page 17, lines 5 - 6 ). There is no indication or appreciation of synergistic interaction to combine the amino acids in Blackburn with the therapeutic method in Walser to achieve the present invention.

Ito discloses anti-stress agents for animals and a method for reducing stress in animals. Specifically, Ito teaches L-ascorbic acid-2-phosphoric acid, a salt thereof and an L-ascorbic acid-2-glucoside as active ingredients. Although Vitamin C combination with oligosaccharides are allegedly shown by relying on 2-O-.alpha.-D-glucopyranosyl-L-ascorbate (col. 6, line 41), there is no teaching or suggestion that another anti-stress agent can also be used and that it will enhance the anti-stress effect in combination with the amino acid.

Finally, Daley discloses the use of metyrapone to treat wounds in a cat with pituitary dependant hyperadrenocorticism. Similar to Walser, Daley does not indicate that metyrapone is used as an anti-stress agent or its use with particular amino acids as required by the present invention.

Therefore, neither Blackburn, Walser, Ito nor Daley have suggestion or incentive to combine these references together to achieve the present invention. Even if combined, they do

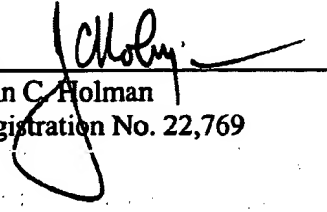
not teach or suggest the invention as presently claimed. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103 be withdrawn.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

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